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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

#### **CMS-1667-PN**

### **Medicare Program; Request for an Exception to the Prohibition on Expansion of Facility Capacity under the Hospital Ownership and Rural Provider Exceptions to the Physician Self-Referral Prohibition**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed notice.

**SUMMARY:** The Social Security Act prohibits a physician-owned hospital from expanding its facility capacity, unless the Secretary of the Department of Health and Human Services (the Secretary) grants the hospital's request for an exception to that prohibition after considering input on the hospital's request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services (CMS) has received a request from a physician-owned hospital for an exception to the prohibition against expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the physician-owned hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition against expansion of facility capacity.

**DATES:** Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 30 days after date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, please refer to file code CMS-1667-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this exception request to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1667-PN

P.O. Box 8010

Baltimore, MD 21244-1850

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Department of Health and Human Services,

Attention: CMS-1667-PN,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

POH-ExceptionRequests@cms.hhs.gov.

**SUPPLEMENTARY INFORMATION:****Inspection of Public Comments:**

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received:

<http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

We will allow stakeholders 30 days from the date of this notice to submit written comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of this notice, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please phone 1-800-743-3951.

**I. Background**

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law-- (1) prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those DHS furnished as a result of a prohibited referral.

Section 1877(d)(2) of the Act provides an exception for physician ownership or investment interests in rural providers (the “rural provider exception”). In order for an entity to qualify for the rural provider exception, the DHS must be furnished in a rural area (as defined in section 1886(d)(2) of the Act) and substantially all the DHS furnished by the entity must be furnished to individuals residing in a rural area.

Section 1877(d)(3) of the Act provides an exception, known as the hospital ownership exception, for physician ownership or investment interests held in a hospital located outside of Puerto Rico, provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

Section 6001(a)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (hereafter referred to together as “the Affordable Care Act”) amended the rural provider and hospital ownership exceptions to the physician self-referral prohibition to impose additional restrictions on physician ownership and investment in hospitals and rural providers. Since March 23, 2010, a physician-owned hospital that seeks to avail itself of either exception is prohibited from expanding facility capacity unless it qualifies as an “applicable hospital” or “high Medicaid facility” (as defined in sections 1877(i)(3)(E), (F) of the Act and 42 CFR 411.362(c)(2), (3) of our regulations) and has been granted an exception to the prohibition by the Secretary of the Department of Health and Human Services (the Secretary). Section 1877(i)(3)(A)(ii) of the Act provides that individuals and entities in the community in which the provider requesting the exception is located must have an opportunity to provide input with

respect to the provider's application for the exception. For further information, we refer readers to the CMS website at:

[http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician\\_Owned\\_Hospitals.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html).

## **II. Exception Request Process**

On November 30, 2011, we published a final rule in the **Federal Register** (76 FR 74122, 74517 through 74525) that, among other things, finalized §411.362(c), which specified the process for submitting, commenting on, and reviewing a request for an exception to the prohibition on expansion of facility capacity. We published a subsequent final rule in the **Federal Register** on November 10, 2014 (79 FR 66770) that made certain revisions. These revisions included, among other things, permitting the use of data from an external data source or data from the Hospital Cost Report Information System (HCRIS) for specific eligibility criteria.

As stated in regulations at §411.362(c)(5), we will solicit community input on the request for an exception by publishing a notice of the request in the **Federal Register**. Individuals and entities in the hospital's community will have 30 days to submit comments on the request. Community input must take the form of written comments and may include documentation demonstrating that the physician-owned hospital requesting the exception does or does not qualify as an "applicable hospital" or "high Medicaid facility," as such terms are defined in §411.362(c)(2) and (3). In the November 30, 2011 final rule (76 FR 74522), we gave examples of community input, such as documentation demonstrating that the hospital does not satisfy one or more of the data criteria or that the hospital discriminates against beneficiaries of Federal health programs; however, we noted that these were examples only and that we will not restrict the type of community input that may be submitted. If we receive timely comments from the

community, we will notify the hospital, and the hospital will have 30 days after such notice to submit a rebuttal statement (§411.362(c)(5)).

A request for an exception to the facility expansion prohibition is considered complete as follows:

- If the request, any written comments, and any rebuttal statement include only HCRIS data: (1) the end of the 30-day comment period if CMS receives no written comments from the community; or (2) the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§411.362(c)(5)(i)).
- If the request, any written comments, or any rebuttal statement include data from an external data source, no later than: (1) 180 days after the end of the 30-day comment period if CMS receives no written comments from the community; and (2) 180 days after the end of the 30-day rebuttal period if CMS receives written comments from the community, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement (§411.362(c)(5)(ii)).

If we grant the request for an exception to the prohibition on expansion of facility capacity, the expansion may occur only in facilities on the hospital's main campus and may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed to exceed 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds (§411.362(c)(6)). The CMS decision to grant or deny a hospital's request for an exception to the prohibition on expansion of facility capacity must be published in the **Federal Register** in accordance with our regulations at §411.362(c)(7).

### **III. Hospital Exception Request**

As permitted by section 1877(i)(3) of the Act and our regulations at §411.362(c), the following physician-owned hospital has requested an exception to the prohibition on expansion of facility capacity:

Name of Facility: Deaconess Women's Hospital of Southern Indiana

d/b/a The Women's Hospital

Location: 4199 Gateway Blvd

Newburgh, IN 47630

Basis for Exception Request: High Medicaid Facility

We seek comments on this request from individuals and entities in the community in which the hospital is located. We encourage interested parties to review the hospital's request, which is posted on the CMS website at: [http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician\\_Owned\\_Hospitals.html](http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals.html). We especially welcome comments regarding whether the hospital qualifies as a high Medicaid facility. Under §411.362(c)(3), a high Medicaid facility is a hospital that satisfies all of the following criteria:

- Is not the sole hospital in the county in which the hospital is located.
- With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.
- Does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Individuals and entities wishing to submit comments on the hospital's request should

review the “**DATES**” and “**ADDRESSES**” sections and state whether or not they are in the community in which the hospital is located.

#### **IV. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

#### **V. Response to Public Comments**

We will consider all comments we receive by the date and time specified in the “**DATES**” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.



CMS-1667-PN

**Dated:** July 14, 2016

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**Andrew M. Slavitt**

Acting Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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